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| APPLICATION NO.                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/045,730  | 10/19/2001  | Paul Arthur Mason    | 10071-018-999       | 9664             |
| 20583   | 7590        | 12/11/2006           | EXAMINER            |                  |
| JONES DAY<br>222 EAST 41ST ST<br>NEW YORK, NY 10017 |             |                      | GHALI, ISIS A D     |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1615                |                  |

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/045,730

Applicant(s)

MASON, PAUL ARTHUR

Examiner

Isis A. Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5,6,12,15,16,22,26,27,55,56,59-65,68 and 69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,12,15,16,22,26,27,55,56,59-65,68 and 69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 09/14/2006.

The receipt is acknowledged of summary of the interview held on September 05, 2006 with applicants' representative Mr. Jones Day, filed 09/14/2006.

Claims 2-4, 7-11, 13, 14, 17-21, 23-25, 28-54, 57, 58, 66 and 67 have been canceled.

Claims 1, 5, 6, 12, 15, 16, 22, 26, 27, 55, 56, 59-65, 68 and 69 are pending and included in the prosecution.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/14/2006 has been entered.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 5, 6, 12, 15, 16, 22, 26, 27, 55, 56, 59-65, 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,405,366 ('366) combined with US 5,306,504 ('504) and US 5,660,178 ('178).

US '366 teaches a non-stingy adhesive hydrogel that can be formed into patches and wound dressings for long term application of a pharmaceutically active agents to a patient and having both adhesive and cohesive properties (abstract; col.4, lines 30-31).

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The patches and wound dressing are sterile and packaged to ensure sterility (col.5, lines 36-55). The patch must be sterile and the patch and the associated structural and packaging material are sterilized (col.5, lines 35-55). The hydrogel comprises cross-linked polyvinyl pyrrolidone (PVP) in an amount from about 10 to about 30% (col.6, lines 35-37, 47-49). The hydrogel patch comprises up to 50% and preferable more than 5% of pharmaceutically active agent including lidocaine (col.19, lines 60-68; col.20, lines 6-8, 12). The hydrogel further comprises preservative including paraben (col.8, lines 5, 10; col.8, lines 15-22). The hydrogel is coated on a backing of polyester (col.9, lines 1-13).

However, US '366 does not teach the breathable backing material as required by the claims.

US '504 teaches hydrogel based on cross-linked PVP useful for burn and wound dressings, and transdermal devices (abstract; col.3, lines 51-60). The hydrogel comprises up to 10% of active agent including lidocaine (col.3, lines 40-45). The hydrogel wound dressing is provided on a backing that control moisture vapor permeability (col.4, lines 5-8; col.5, lines 62-65). Hence, the art recognized providing hydrogel on breathable backing to control moisture vapor permeability.

US '178 teaches pressure sensitive adhesive for transdermal drug delivery devices having a baking material of high moisture vapor transmission including the trademark HYTREL that is disclosed by applicants as polyester polyether copolymer (abstract; col. 12, lines 3-11). HYTREL is expected to have the same ranges of moisture vapor transmission rate as instantly claimed.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide sterile packaged patch or wound dressing comprising hydrogel comprising cross-linked PVP and lidocaine on a backing as disclosed by US '366, and replace the backing disclosed by US '366 by a backing that control moisture vapor permeability as disclosed by US '504, motivated by the teaching of US '504 that kind of backing are suitable for transdermal devices and wound dressing comprising hydrogel, and further replace the backing that control moisture vapor permeability by HYTREL backing that have high moisture vapor transmission disclosed by US '178 as suitable for transdermal adhesive patches, motivated by the teaching of US '178 that such backing have high moisture vapor transmission, therefore suitable for the skin application, with reasonable expectation of having patch or wound dressing comprising hydrogel comprising cross-linked PVP to deliver lidocaine and having a backing of HYTREL that have a high moisture vapor transmission to allow breathing of the underlying skin, as desired by applicants.

The combination of the references does not teach the specific mixture of preservative as claimed in claim 62. However, the specific preservative mixture does not impart patentability to the claims, absent evidence to the contrary. US '366 suggested mixture of preservatives, and one having ordinary skill in the art would have selected the specific preservative mixtures to provide synergistic preservative effect on the hydrogel.

### ***Response to Arguments***

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5. Applicant's arguments with respect to claims 1, 5, 6, 12, 15, 16, 22, 26, 27, 55, 56, 59-65, 68 and 69 have been considered but are moot in view of the new ground(s) of rejection.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,143,071 disclosed PVP hydrogel to deliver anesthetic to the skin and comprises phenoxyethanol.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali  
Primary Examiner  
Art Unit 1615

*Isis Ghali*

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